UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

February 27, 2008

MEMORANDUM

SUBJECT: **Naphthalene**: Review of "Estimation of Homeowner Exposure to LX1298-01 (Naphthalene) Resulting from Simulated Residential Use as an Insect Repellent (MRID 437165-01)" DP Barcode: 340008, PC Code: 055801

FROM: Wade Britton, MPH, Industrial Hygienist
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THROUGH: Catherine Eiden, Branch Chief
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This document serves as a data evaluation record for a naphthalene exposure study, "Estimation of Homeowner Exposure to LX1298-01 (Naphthalene) Resulting from Simulated Residential Use as an Insect Repellent (MRID 437165-01)," submitted by Recochem Inc. in support of the registration of naphthalene. The purpose of this study was to estimate the potential for inhalation exposure of homeowners to naphthalene during and after a single application of LX1298-01. In addition, dermal exposure to the homeowner's hands during application and post-application indoor air concentrations of naphthalene were estimated. A primary review of this study was conducted by Versar, Inc. under the guidance of HED (see Attachment). The following is a summary of the study and its findings.

Received in RRC 3/4/2008 Mary Simmons

Study Design and Sampling

LX1298-01, a mothball formulation, containing 99.5% (0.995 g ai/g product) of the active ingredient (ai) naphthalene, was applied as an insect repellent by placing mothballs in a closet and a dresser drawer at the maximum application rate of 1.0 lb ai/50 ft^3 in designated bedrooms at three different locations near Valdosta, Georgia. The person weighing out the mothballs and placing them in the closet and dresser drawer at each location was monitored for inhalation exposure and dermal exposure of naphthalene to the hands. After the application, the treated room was closed and not entered for three days. At the beginning of the fourth day, indoor air concentration sampling at three locations within the treated room was monitored continuously for 8-hour intervals for three consecutive days. During a 12-hour period of each sampling day (4, 5 and 6 days after treatment (DAT)) a worker wearing a personal air sampling device (two-stage charcoal filter cartridge) entered the treated room every two hours for a 15-minute sampling duration to simulate a homeowner's or worker's daily activities in the room. Indoor air concentration samples were also collected at three, 15-minute intervals during this same 12-hour period inside the treated closet and inside the treated drawer. Dermal exposure to the applicator was determined by analysis of gloves worn when weighing out and applying the test product.

Results

The overall average naphthalene applicator hand exposure was either 9.91E-05 or 1.30E-04 mg/cm^2, depending on whether or not an unidentified sample provided in the report can be clarified. The applicator inhalation exposure data mentioned in the written Study Report were not provided. Post-application inhalation exposure and air concentration was monitored on Days 4, 5 and 6 after the application. The overall average post-application inhalation exposures for Days 4, 5 and 6 were 773 $\mu g/m^3$ (123 µg/day), 867 $\mu g/m^3$ (217 µg/day) and 900 $\mu g/m^3$ (225 µg/day), respectively. Air monitoring took place within the treated zones (dresser drawer and closed closet). However, the Study Author only provided naphthalene air concentrations for Hour 0, Hours 4-8, and Hour 12. These concentrations ranged for all three trials from 2.37 to 10.3 µg/L in the dresser drawer and from 1.49 to 12.29 µg/L in the closet for all three days. The air sampling devices monitoring the areas outside the treated zone were placed just outside the closet, on top of the dresser and adjacent to the head of the bed. The average 24-hour naphthalene air concentration on top of the dresser at all three test sites on Days 4, 5 and 6 ranged from 0.39 to 0.89 µg/L. The average 24-hour naphthalene air concentration adjacent to the closet at all three test sites on Days 4, 5 and 6 ranged from 0.43 to 0.81 µg/L. The average 24-hour naphthalene air concentration at the head of the bed at all three test sites on Days 4, 5 and 6 ranged from 0.39 to 0.86 µg/L.

Study Limitations

There were a number of issues of concern with this study which did not meet the 875.1200, 875.1400 and 875.2500 guidelines. The following issues of potential concern were identified:

- Raw data were not provided for verification purposes.
- Post application re-entry exposure was monitored on days 4,5,6 after application. This is not a worst case scenario. It is highly likely that residents will enter the drawers and closet immediately after application.
- Application exposure monitored application of mothballs to one bedroom only (drawer and closet). This is not a worst case scenario. It is possible for a resident to apply to more than one bedroom/day.
- A study protocol was not provided.
- A formulated product label was not provided. EPA provided a "Naphthalene Technical" label, but it did not provide application rates or the protective clothing requirements for the formulated product.
- There were only three applicators monitored in this study.
- If the actual duration for each applicator replicate was recorded, it was not reported in the study.
- Information about the workers in this study was not provided.
- Laboratory fortification recoveries were not discussed in this study.
- The flow rate used for inhalation exposure monitoring was 0.5 L/min. Current guidelines recommend a flow rate of at least 2.0 L/min.
- Charcoal filter tube field fortification samples were prepared but the results were not discussed in this study.
- Field fortification samples were not prepared for the cotton gloves which were used for applicator dermal exposure.
- Storage stability of naphthalene in frozen storage was not discussed.
- According to the study, applicator inhalation exposure was monitored, but the results were not provided in the study report.

- Post application exposure monitoring included inhalation exposure only. Potential dermal exposure was not discussed or examined.

- It is not known if trapping efficiency was addressed prior to this study.

- It is not known if any breakthrough testing was done prior to this study.

- The study did not mention metabolites or breakdown products.

- According to the guidelines, background sampling is to be done prior to the start of exposure activities. Background sampling (control samples) occurred simultaneously with the post-application exposure activities rather than before them.

- According to the guidelines, inhalation exposure studies must be carried out concurrently with dermal exposure and transferable residue studies. Transferable residue studies were not performed concurrently with this study and only applicator hand exposure was monitored.

- Indoor sampling devices for air monitoring were set at 5 feet above the floor to simulate an adult's breathing zone. There were no samplers set lower to the floor to represent exposure to children.

- The results for the method validation were presented in the study report without addressing what matrix was used. The limit of detection (LOD) for this method was 5.0 picograms (5.0E-06 µg). The limit of quantitation (LOQ) for this method was not provided.

- There was no recovery data provided in this study to determine if correction of the raw data was required.

Attachment

STUDY TYPE: Applicator Passive Dosimetry Study Using Glove Dosimetry and Inhalation Monitoring.
Residential Indoor Post-Application Inhalation Monitoring Study
Residential Indoor Air Concentration Monitoring Study

TEST MATERIAL: LX1298-01, mothball formulation containing 99.5% naphthalene as the active ingredient.

SYNONYMS: Naphthalene, LX1298-01 (CAS # 91-20-3);

CITATION:

Author:	T. Bill Waggoner
Title:	*Estimation of Homeowner Exposure to LX1298-01 (Naphthalene) Resulting from Simulated Residential Use as an Insect Repellent* (100 pages)
Report Date:	October 7, 1994
Performing Laboratory:	Pharmaco LSR Inc. Mettlers Road East Millstone, NJ 08875
Identifying Codes:	Pharmaco LSR Study Number: 93-9083; MRID 437165-01; Unpublished.

SPONSOR: Recochem, Incorporated
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EXECUTIVE SUMMARY:

The purpose of this study was to estimate the potential for inhalation exposure of homeowners to naphthalene during and after a single application of LX1298-01. Dermal exposure to the homeowner's hands during application and post-application indoor air concentrations of naphthalene were also estimated. LX1298-01, a mothball formulation, containing 99.5% (0.995 g ai/g product) of the active ingredient (ai) naphthalene, was applied as an insect repellent by placing mothballs in a closet and a dresser drawer at the maximum application rate of 1.0 lb ai/50 ft^3 in designated bedrooms at three different locations near Valdosta, Georgia. The person weighing out the mothballs and placing them in the closet and dresser drawer at each location was monitored for inhalation exposure and dermal exposure of naphthalene to the hands. After the application, the treated room was closed and not entered for three days. At the beginning of the fourth day, indoor air concentration sampling at three locations within the treated room was monitored continuously for 8-hour intervals for three consecutive days. During a 12-hour period of each sampling day (4, 5 and 6 days after treatment (DAT)) a worker wearing a personal air sampling device (two-stage charcoal filter cartridge) entered the treated room every two hours for a 15-minute sampling duration to simulate a homeowner's or worker's daily activities in the room. Indoor air concentration samples were also collected at three, 15-minute intervals during this same 12-hour period inside the treated closet and inside the treated drawer.

Dermal exposure to the applicator was determined by analysis of gloves worn when weighing out and applying the test product. The overall average naphthalene applicator hand exposure was either 9.91E-05 or 1.30E-04 mg/cm^2, depending on whether or not an unidentified sample provided in the report can be clarified. The applicator inhalation exposure data mentioned in the written Study Report were not provided. Post-application inhalation exposure and air concentration was monitored on Days 4, 5 and 6

after the application. The overall average post-application inhalation exposures for Days 4, 5 and 6 were 773 μg /m^3 (123 μg/day), 867 μg /m^3 (217 μg/day) and 900 μg /m^3 (225 μg/day), respectively. Air monitoring took place within the treated zones (dresser drawer and closed closet). However, the Study Author only provided naphthalene air concentrations for Hour 0, Hours 4-8, and Hour 12. These concentrations ranged for all three trials from 2.37 to 10.3 μg/L in the dresser drawer and from 1.49 to 12.29 μg/L in the closet for all three days. The air sampling devices monitoring the areas outside the treated zone were placed just outside the closet, on top of the dresser and adjacent to the head of the bed. The average 24-hour naphthalene air concentration on top of the dresser at all three test sites on Days 4, 5 and 6 ranged from 0.39 to 0.89 μg/L. The average 24-hour naphthalene air concentration adjacent to the closet at all three test sites on Days 4, 5 and 6 ranged from 0.43 to 0.81 μg/L. The average 24-hour naphthalene air concentration at the head of the bed at all three test sites on Days 4, 5 and 6 ranged from 0.39 to 0.86 μg/L.

There were a number of issues of concern with this study which did not meet the 875.1200, 875.1400 and 875.2500 guidelines. The following issues of potential concern were identified:

- Raw data were not provided for verification purposes.
- Post application reentry exposure was monitored on days 4,5,6 after application. This is not a worst case scenario. It is highly likely that residents will enter the drawers and closet immediately after application.
- Application exposure monitored application of mothballs to one bedroom only (drawer and closet). This is not a worst case scenario. It is possible for a resident to apply to more than one bedroom/day.
- A study protocol was not provided.
- A formulated product label was not provided. EPA provided a "Naphthalene Technical" label, but it did not provide application rates or the protective clothing requirements for the formulated product.
- There were only three applicators monitored in this study.
- If the actual duration for each applicator replicate was recorded, it was not reported in the study.
- Information about the workers in this study was not provided.
- Laboratory fortification recoveries were not discussed in this study.
- The flow rate used for inhalation exposure monitoring was 0.5 L/min. Current guidelines recommend a flow rate of at least 2.0 L/min.
- Charcoal filter tube field fortification samples were prepared but the results were not discussed in this study.
- Field fortification samples were not prepared for the cotton gloves which were used for applicator dermal exposure.
- Storage stability of naphthalene in frozen storage was not discussed.
- According to the study, applicator inhalation exposure was monitored, but the results were not provided in the study report.
- Post application exposure monitoring included inhalation exposure only. Potential dermal

exposure was not discussed or examined.

- It is not known if trapping efficiency was addressed prior to this study.
- It is not known if any breakthrough testing was done prior to this study.
- The study did not mention metabolites or breakdown products.
- According to the guidelines, background sampling is to be done prior to the start of exposure activities. Background sampling (control samples) occurred simultaneously with the post-application exposure activities rather than before them.
- According to the guidelines, inhalation exposure studies must be carried out concurrently with dermal exposure and transferable residue studies. Transferable residue studies were not performed concurrently with this study and only applicator hand exposure was monitored.
- Indoor sampling devices for air monitoring were set at 5 feet above the floor to simulate an adult's breathing zone. There were no samplers set lower to the floor to represent exposure to children.
- The results for the method validation were presented in the study report without addressing what matrix was used. The limit of detection (LOD) for this method was 5.0 picograms (5.0E-06 µg). The limit of quantitation (LOQ) for this method was not provided.
- There was no recovery data provided in this study to determine if correction of the raw data was required.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. The study sponsor waived claims of confidentiality within the scope of FIFRA Section 10(d) (1) (A), (B), or (C). The study was conducted under EPA Good Laboratory Practice Standards (40 CFR part 160), with no exceptions.

GUIDELINES OR PROTOCOL FOLLOWED:

OPPTS Series 875 Group A - Applicator Exposure Monitoring Test Guidelines (Guidelines 875.1200-indoor dermal exposure and 875.1400-indoor inhalation exposure), and Group B- Post Application Exposure Monitoring Test Guidelines (Guidelines 875.2500- inhalation exposure and air monitoring) of the Pesticide Assessment Guidelines were followed for the compliance review of this study.

CONCURRENT DISLODGEABLE RESIDUE DISSIPATION STUDY?: No

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Material:

Formulation:	LX1298-01, a mothball formulation, containing 99.5% (0.995 g ai/g product) of the active ingredient (ai) naphthalene.
Lot/Batch # technical:	Not provided.
Lot/Batch # formulation:	29 22 10.
Purity:	A sponsor-provided certificate of analysis listed the percent active ingredient as 99.5% w/w with an expiration date of October 22, 1995.

CAS #(s): The CAS # for naphthalene is 91-20-3
Other Relevant Information: EPA Registration No. 43841-1

2. Relevance of Test Material to Proposed Formulation(s):

The test product used in this study was referred to as LX1298-01 formulated as mothballs. A label was not provided with the Study Report and Versar was unable to locate a label on EPA's PPLS website. EPA provided a label for "Naphthalene Technical" and a code name certification form saying that LX1298-01 was synonymous with Naphthalene Technical. The Naphthalene technical label was not for the end use product formulated as moth balls and there were no application rates listed.

3. Packaging:

Naphthalene formulated as mothballs was received at each test location packaged in a single, 3.0 kg container.

B. STUDY DESIGN

A study protocol was not provided with the Study Report. The Study Report did not list any amendments to the study protocol. There were two deviations to the Study Report. The first deviation involved a change in the spiking procedures for the field fortification samples. The study protocol only required the filter tubes be spiked with 25 µL of the spiking solution. The Study Director requested that a second set of field fortification samples be spiked at 10 µL and also requested an additional spike be prepared using 25 µL of toluene. The second deviation involved the sampling duration of two air monitoring samples. Two samples were not collected for the entire sample duration time due to equipment problems. These samples were LA93-4736 from trial 92-298-01-21H-02 and LA93-4838 from trial 92-298-01-21H-03. The desired sample duration time was eight hours. LA93-4736 had a duration time of only four hours and sample LA93-4838 was five hours and 51 minutes. These deviations did not compromise the scientific integrity of this study.

1. Number and Type of Workers and Sites:

Three trials were conducted in and near Valdosta, Georgia. Three residences of similar design were utilized in the study. Each residence was a single story, three bedroom, residence ranging in size from approximately 1,800 to 2,400 ft^2. The temperature was controlled at each site using central heating and air-conditioning. Each test site was set up in a similar manner, with a rectangular shaped bedroom with only one entrance and a single closet that only opened into the subject bedroom, containing one bed and at least one set of dresser drawers.

For trial number 92-298-01-21H-02, the treated bedroom measured approximately 154 ft^2 with a closet of approximately 13.6 ft^2. A set of bi-fold doors was used to close off the closet from the rest of the room. The bed was located on the opposite wall approximately 6 ft from the closet door, and the dresser was located on the wall adjacent to the wall with the closet, approximately 6 ft from the closet door. The non-treated room was located approximately 40 ft from the treated room at the opposite end of the residence.

For trial number 92-298-01-21H-03, the treated bedroom measured approximately 106 ft^2 with a closet of approximately 8.1 ft^2. A single solid door was used to close off the closet from the rest of the room. The bed was located on the opposite wall approximately 5.5 ft from the closet, and the dresser was located on the wall adjacent to the wall with the closet, approximately 2 ft from the closet door. The non-treated room was located approximately 30 ft from the treated room at the opposite end of the residence.

For trial number 92-298-01-21H-04, the treated bedroom measured approximately 143 ft^2 with a closet of approximately 8.8 ft^2. A single solid door was used to close off the closet from the rest of the room. The bed was located on an adjacent wall to the closet and was approximately 2 to 3 ft from the closet door. The

dresser was located approximately 6 to 7 ft from the closet door and 4 to 5 ft from the bed. The non-treated room was located approximately 30 ft from the treated room at the opposite end of the residence.

One worker (applicator) was monitored per residence. The Study Report did not mention the number of workers used to collect the post-application inhalation samples at each residence. Information concerning the workers (i.e. sex, age, weight and experience) was not provided.

2. Replicates:

There was one applicator replicate per test site for a total of 3 applicator dermal (hand) and inhalation exposure replicates. The exact duration of each application was not provided in the study. The applicator replicates would weigh the mothballs and put them into a container during placement and use in their respective locations. After placement, the applicator would close the door(s) to the closet and the dresser drawer and then exit the room.

For the post-application inhalation exposure portion of the study there were seven 15-minute sampling intervals over a 12-hour period on Days 4, 5 and 6 after the application for a total of 21 replicates per test site (63 total replicates for the study). The indoor inhalation samples collected from the sampling unit attached to the person who entered the room were used to simulate a homeowner who would normally enter the bedroom on a regular basis during the day.

For the post-application air monitoring, at each test site there was one stationary air sampler located in the closet and one inside the treated dresser drawer. The stationary air samplers in the treated zones (closet and drawer) were run for three 15-minute intervals during the same 12-hour period as the post-application inhalation exposure monitoring on Days 4, 5 and 6 after the application. This resulted in three closet replicates and three drawer replicates per sampling day for a total 9 closet air replicates and 9 drawer replicates for each test site (total of 27 closet air replicates and 27 drawer replicates for the study).

Also for the post-application air monitoring, there were three stationary air samplers located within the room (one outside the closet door, one on top of the dresser and one at the head of the bed). The stationary air samplers outside the treated zones but inside the room were run continuously and samples were collected at each 8-hour interval for Days 4, 5 and 6 after the application resulting in three outside closet replicates, three dresser top replicates and three bed replicates per sampling day for a total of 27 room replicates per test site and 81 post-application stationary room air replicates for the study.

3. Protective Clothing:

Protective clothing worn by the applicator was not discussed in the Study Report. The Naphthalene Technical label stated that protective gloves and safety goggles or face shield should be worn when handling the molten product. It is not certain if these protective clothing measures would follow over to the end use product.

4. Time Interval(s) for Re-entry:

Post-application inhalation/air monitoring sampling intervals occurred on Days 4, 5 and 6 after the application.

5. Application Rates and Regimes:

Application Rate(s): The application method used in this study simulated the typical use of the test product as an insect repellent in a typical residential situation. The test product was applied at a target application rate of 320 g ai/m^3 (1.0 lb ai/50 ft^3). Label recommended application rates for the LX1298-01 end use product were not available. The amount of test product to be placed in each location in the room was based on the size of the closet and the dresser drawer where the mothballs were to be placed. Based on the calibration documentation for the closets at each test site, 1.002,

0.997, and 0.998 lb ai/50 ft^3 were applied to the three test sites, respectively. Based on the calibration documents for the dresser drawers at each test site 1.268, 0.964, and 0.958 lb ai/50 ft^3 were applied to the three trials, respectively. According to the Study Report, any differences in rate of the test product applied and the rate specified in the protocol were due to the requirement that the test product be applied to the nearest "whole" mothball. After application, the room was closed for three days and no one entered the room until Day 4 after the application.

Application Equipment and Method:	An electronic analytical balance was used to weigh out the test product.
Spray Volume:	Not applicable to this study.
Equipment Calibration Procedures:	According to the Study Report, all of the equipment used to weigh out the test product was cleaned and calibrated prior to each application.

6. <u>Exposure Monitoring Methodology</u>:

Applicator Dermal Exposure:	Applicator dermal exposure was measured using cotton gloves. The gloves were collected immediately after the application, placed into sealed plastic bags, then placed in a freezer, and stored until the samples were shipped to the analytical laboratory.

Application Inhalation Exposure:

At the time of the application of the test product, the applicator wore an air sampler pump with the filter tube attached to the applicator's shirt collar in the applicator's breathing zone. The air sampling pump was turned on and allowed to run from the time the applicator began making the calculations of the test product through the weighing and actual application of the test product. After the test product had been placed in the appropriate locations (the closet and the dresser drawer), the applicator left the room and turned the sampler off. All of the samples consisted of a two-stage charcoal filter tube/cartridge through which air had been pulled at a constant rate over a certain period of time. All air sampling pumps were calibrated prior to each used to pull a constant flow rate of approximately 500 mL/min through the charcoal filter tubes. When the monitoring period was completed, the tube was removed from the air pump, immediately capped, and placed in a labelled, whirl-pak plastic bag. The bag was then sealed, placed in a freezer as soon as possible, and stored until the samples were shipped to the analytical laboratory.

Post-Application Inhalation Exposure:

After the application, each room was closed for three days and not entered until Day 4 after the application. Potential post-application inhalation exposure was monitored on the beginning of Day 4 by attaching a sampler unit to a person that entered the bedroom several times daily during the three-day post-application sampling period (Day 4, 5 and 6 after the application). The filter tube was attached to the person's shirt collar in his/her breathing zone. The air sampling pump was turned on and the worker entered the room. Once inside the room, the worker proceeded to the dresser drawer containing the test product, opened the drawer, and stood facing the drawer for approximately 10 to 20 seconds. The worker then closed the drawer and proceeded to the treated closet. The closet door was then opened, the worker stepped into the closet, and remained there for 15 to 30 seconds before exiting and closing the closet door. After these two steps were completed, the worker remained in the bedroom for the rest of the 15-minute monitoring duration simulating tasks a homeowner might do while in the room (i.e., dusting, folding clothes, sitting in a chair, etc.). At the end of the 15-minute sampling period, the

worker left the room and turned off the sampler pump. All of the samples consisted of a two-stage charcoal filter tube/cartridge through which air had been pulled at a constant rate over a certain period of time. All air sampling pumps were calibrated prior to each used to pull a constant flow rate of approximately 500 mL/min through the charcoal filter tubes. Inhalation exposure was monitored for seven 15-minute sampling intervals over a 12-hour period on each of Days 4, 5 and 6 after the application. Once each sampling period was completed, the tube was removed from the air pump, immediately capped, and placed in a labelled, whirl-pak plastic bag. The bag was then sealed, placed in a freezer as soon as possible, and stored until the samples were shipped to the analytical laboratory.

Post-Application Air Monitoring:

Post-application stationary air monitoring was performed at 5 locations within the room at each test site. Two of the air monitoring locations were within the treated zones (one in the closet and one in the dresser drawer). The three remaining locations were within the room (one adjacent to the closet, one on top of the dresser and one at the head of the bed). All of the samples consisted of a two-stage charcoal filter tube/cartridge through which air had been pulled at a constant rate over a certain period of time. All air sampling pumps were calibrated prior to each used to pull a constant flow rate of approximately 500 mL/min through the charcoal filter tubes.

The stationary air samplers in the treated zones (closet and drawer) were run for three 15-minute intervals during the same 12-hour period as the post-application inhalation exposure monitoring on Days 4, 5 and 6 after the application. Each time the sample was collected from the dresser drawer, a person would enter the room, open the drawer, place the entire sampling unit inside the drawer, turn on the air pump, and then close the drawer. The dresser drawer remained closed for the 15-minute sample duration after which the sampler pump was turned off and the entire sampler unit removed. The stationary air sampling device for the closet was placed on a side wall in the closet 1.5 meters (approximately 5 ft) above the floor. To collect the sample from the closet a person would open the closet door, step inside the closet, and place the sample pump on a shelf. Then, the sample tube holder containing the sample tube was affixed to the wall of the closet 1.5 meters above the floor and the air pump turned on. The unit was allowed to run for 15 minutes. The pump was then cut off and the entire sampling unit removed. Once each sampling period for a designated sampling point was completed, the tube was removed from the air pump, immediately capped, and placed in a labelled, whirl-pak plastic bag. The bag was then sealed, placed in a freezer as soon as possible, and stored until the samples were shipped to the analytical laboratory.

The stationary air samplers outside the treated zones but inside the room were run continuously and samples were collected at each 8-hour interval for Days 4, 5 and 6 after the application. One of the stationary samplers was located on top of the dresser containing the test product. Another stationary sampler was located just outside the closet door approximately 1.5 meters above the floor. The third stationary sampler was placed at the head of the bed. When the 8-hour sampling interval was completed, the pumps were turned off and another unit which had been calibrated and fitted with a fresh sample tube was immediately turned on so that sampling was uninterrupted. The unit for the just completed sample interval was then removed. Once each sampling period for a designated sampling point was completed, the tube was removed from the air pump, immediately capped, and placed in a labelled, whirl-pak plastic bag. The bag was then sealed, placed in a freezer as soon as possible, and stored until the samples were shipped to the analytical laboratory.

7. Re-entry Scenario:

After the application, the room was closed for 3 days. On the beginning of the fourth day air monitoring and post-application inhalation sampling began.

8. Analytical Methodology:

Extraction Method(s): For each pair of gloves, the entire glove was extracted with toluene. The toluene and gloves were placed on a shaker apparatus for five minutes. An aliquot from each glove extract was evaporated to near dryness and diluted to 1.0 mL final volume with toluene. Naphthalene was then determined under gas chromatograph.

The extraction of naphthalene from charcoal was done using toluene. The naphthalene was desorbed from the charcoal tube and the extract was diluted as needed into the standard range and injected into a gas chromatograph.

Detection Method(s): See Table 1 for a summary of the GC/FID conditions.

Table 1. Summary of Gas Chromatograph/Flame Ionization Detection Conditions

Instrument:	Hewlett Packard 5890 Series II gas chromatograph equipped with a flame ionization detector
GC Column:	J&W, DB-5, 30 m column length, 0.32 mm i.d, 0.25 µm film thickness
Carrier Flow Rate:	2.80 mL/min.
Make-Up Flow Rate:	27.2 mL/min.
Air Flow Rate:	400 mL/min.
Hydrogen Flow Rate:	40.0 mL/min.
Sample Size:	1.00 µL
Column Temperature:	Initial: 40 °C Time: 1.50 min. Rate A: 10 °C /min. Final temp. A: 150 °C Rate B: 20 °C /min. Final temp B: 200 °C
Injector Temperature:	200°C
Detector Temperature:	250°C
Attenuation:	0

Method Validation: For the instrument method validation, five injection standards ranging from 0.50 µg/mL to 20.0 µg/mL were injected in triplicate to establish reproducibility and a linear detector response. For the sample method validation, a control, five high (200 µg) and five low (10 µg) fortifications were extracted. The five low and high fortification samples were analyzed to confirm method extraction reproducibility. One of the low and one of the high fortification samples were injected ten times to determine the instrument reproducibility. There were no detectable naphthalene residues found in the control sample. The mean recovery was 89.9% ± 2.16 (n=28). The limit of detection (LOD) for this method was 5.0 picograms (5.0E-06 µg). The limit of quantitation (LOQ) for this method was not provided in the Study Report. The method validation discussion did not address whether or not the matrix used to collect the naphthalene residues would impact these results. It is not certain what matrix was used in the method validation.

Instrument Performance and Calibration: A standard curve for analysis was constructed by injecting at least three standards at different concentrations. The standard curve is plotted as the peak area of naphthalene versus the nanograms injected. A standard curve is calculated by linear regression.

Quantification: Sample peak area responses were calculated using the standard curve. The sample concentration was calculated by dividing the "ng found" by the "mL injected." The "mL injected" represented the amount of the total volume of air sampled that was injected for analysis.

9. Quality Control:

Lab Recovery: No concurrent laboratory fortified samples were run with the field samples in this study.

Field Blanks: Background levels of naphthalene were determined by collecting air in an untreated room located away from the treated room at each location. Only a single point was sampled within the control room. The sampling method and duration was the same as that used for collection of the stationary air monitoring samples from the treated room (outside the treated zones). Samples of air were collected in 8-hour increments on days 4, 5 and 6. Once each sampling period for a designated sampling point was completed, the tube was removed from the air pump, immediately capped, and placed in a labelled, whirl-pak plastic bag. The bag was then sealed, placed in a freezer as soon as possible, and stored until the samples were shipped to the analytical laboratory. Control samples were stored in a freezer and shipped in a cooler separate from the other samples generated during the trials. The Study Report only provided control residues for test site 92-298-01-21H-02 saying that those levels were typical of all three test sites. The average naphthalene air concentrations in the control room on Day 4, 5 and 6 were 0.030 µg/L, 0.022 µg/L and 0.021 µg/L, respectively. There were no control glove samples analyzed in this study.

Field Recovery: According to the Study Report, air sampling field fortified samples were prepared for each of the three trials conducted. Charcoal filter tubes/cartridges were fortified by opening the inlet end of the tube and spiking the sorbent (charcoal) in the first chamber with either 10 µL or 25 µL of a 1,000 µg/mL standard of naphthalene in toluene. Two tubes were fortified at 10 µL and two tubes were fortified at 25 µL. After fortifying the filter tube, the end was capped and the tube was immediately placed in a labeled whirl-pak bag and sealed. The bagged tubes were placed in frozen storage and then shipped frozen to the analytical laboratory.

On November 4, 1993, an additional set of fortified samples were prepared for the test sites using a fresher spiking solution than what was used before. The first batch of spiking solution had an expiration date of October 7, 1993, while the trials were conducted on or after October 29, 1993. These additional fortified samples were prepared to assure that the spiking solution used in all three trials was valid and that the same spiking solution was used for all three trials. This time only one field fortified sample was prepared at 10 µL and one at 25 µL for each test site.

Although the Study Report discusses the preparation of field fortified samples, the results for these samples were not provided. There was no mention of field fortification samples being prepared for dermal exposure.

Formulation: The test product used was LX1298-01, a mothball formulation, containing 99.5% (0.995 g ai/g product) of the active ingredient (ai) naphthalene.

Tank mix: Tank samples are not applicable for this study.

Travel Recovery: Travel recovery samples were not used for this study.

Storage Stability: A storage stability study was not performed for this study. The total number of days each sample remained in frozen storage from sampling to extraction was not reported. The field fortification recovery results were not provided in the Study Report.

10. Relevancy of Study to Proposed Use:

The study monitored a worker simulating a homeowner performing normal duties involving the application of this product to one bedroom in a residential environment.

II. RESULTS AND CALCULATIONS:

A. EXPOSURE CALCULATIONS:

Applicator Dermal Exposure:

For the applicator exposure portion of the study, cotton gloves were used to determine dermal exposure as the mothballs were placed in the treated zones. The area of gloves corresponding to the palm and fingers was determined indirectly by weighing an area of paper corresponding to the size of the glove and comparing it to the weight of 1 cm^2 of the same type of paper. The area of both gloves (one pair) was calculated to be 407 cm^2. Dermal exposure was calculated assuming that all of the naphthalene residues found on the gloves corresponded to the area of palm and fingers (contact side). Table 2 provides a summary of the applicator hand exposure as mg/cm^2. A fourth set of sample results were provided in the report; however, due to the poor quality of the reproduction of the report, it is unclear where this sample was collected and what it represents. It is also included in Table 2. The overall average naphthalene hand exposure for all three test sites, including and excluding the unknown sample, was 9.91E-05 and 1.30E-04 mg/cm^2, respectively.

Applicator Inhalation Exposure:

Although the Study Report discusses the methodology used to collect the applicator inhalation exposure samples, the results were neither provided nor discussed in the Study Report.

Post-Application Inhalation Exposure:

For the post-application exposure portion of the study, the Study Author provided inhalation exposure values expressed as µg/L using a personal air sampling device. Versar estimated exposure values as µg /m^3 and µg/day. The NAFTA recommended inhalation rate of 16.7 L/min, for light activities, was used by Versar to calculate inhalation exposures.

Post-application inhalation exposures based on residue levels found in the charcoal filter tubes are summarized in Table 3. Naphthalene concentrations were generally constant throughout each day of day 4 to 6, but differed somewhat from one trial to the next. The maximum amount of naphthalene to which an individual was exposed to within a 15-minute exposure time was 1.62 µg/L from Day 6 at trial 92-298-02-21H-03. The overall average post-application inhalation exposures for all three test sites on Days 4, 5 and 6 were 773 µg /m^3 (123 µg/day), 867 µg /m^3 (217 µg/day) and 900 µg /m^3 (225 µg/day), respectively.

Naphthalene Air Concentration:

This study measured the concentration of naphthalene in the air of the treated zones (closet and drawer) beginning four days after the application and ending 6 days after the application. Air samples were collected in the treated zones at 15-minute intervals every two hours during the same 12-hour monitoring period as the post-application inhalation exposure monitoring period. However, the Study Author only provided naphthalene air concentrations expressed as µg/L sampled for Hour 0, Hours 4-8, and Hour 12. The naphthalene air concentrations inside the treated zones for these time periods are summarized in Table 4. For Trial 92-298-01-21H-02, concentrations ranged from 5.29 to 10.3 µg/L in the dresser drawer and from 1.49 to 3.22 µg/L in the closet for all three days. For Trial 92-298-01-21H-03, concentrations ranged from 3.66 to 5.61 µg/L in the dresser drawer and from 8.13 to 12.29 µg/L in the closet for all three days. For Trial 92-298-01-21H-04, concentrations ranged from 2.37 to 9.45 µg/L in the dresser drawer and from 3.71 to 5.99 µg/L in the closet for all three days.

The study also measured the concentration of naphthalene in the air within the same room but just outside the treated zones (on top of the dresser, just outside the closet door and at the head of the bed). The stationary air samplers outside the treated zones but inside the room were run continuously and samples were collected for each 8-hour interval on Days 4, 5 and 6 after the application. A summary of the naphthalene air concentrations outside the treated zones around the room are summarized in Table 5. The average 24-hour naphthalene air concentration on top of the dresser at all three test sites on Days 4, 5 and 6 ranged from 0.39 to 0.89 µg/L. The average 24-hour naphthalene air concentration adjacent to the closet at all three test sites on Days 4, 5 and 6 ranged from 0.43 to 0.81 µg/L. The average 24-hour naphthalene air concentration at the head of the bed at all three test sites on Days 4, 5 and 6 ranged from 0.39 to 0.86 µg/L.

III DISCUSSION

A. LIMITATIONS OF THE STUDY:

There were a number of issues of concern with this study which did not meet the 875.1200, 875.1400 and 875.2500 guidelines. The following issues of potential concern were identified:

- Raw data were not provided for verification purposes.
- Post application re-entry exposure was monitored on days 4,5,6 after application. This is not a worst case scenario. It is highly likely that residents will enter the drawers and closet immediately after application.
- Application exposure monitored application of mothballs to one bedroom only (drawer and closet). This is not a worst case scenario. It is possible for a resident to apply to more than one bedroom/day.
- A study protocol was not provided.
- A formulated product label was not provided. EPA provided a "Naphthalene Technical" label, but it did not provide application rates or the protective clothing requirements for the formulated product.
- There were only three applicators monitored in this study.
- If the actual duration for each applicator replicate was recorded, it was not reported in the study.
- Information about the workers in this study was not provided.
- Laboratory fortification recoveries were not discussed in this study.
- The flow rate used for inhalation exposure monitored was 0.5 L/min. Current guidelines recommend a flow rate of at least 2.0 L/min.

- Charcoal filter tube field fortification samples were prepared but the results were not discussed in this study.

- Field fortification samples were not prepared for the cotton gloves which were used for applicator dermal exposure.

- Storage stability of naphthalene in frozen storage was not discussed.

- According to the study, applicator inhalation exposure was monitored, but the results were not provided in the study report.
- Post application exposure monitoring included inhalation exposure only. Potential dermal exposure was not discussed or examined.

- It is not known if trapping efficiency was addressed prior to this study.

- It is not known if any breakthrough testing was done prior to this study.

- The study did not mention metabolites or breakdown products.

- According to the guidelines, background sampling is to be done prior to the start of exposure activities. Background sampling (control samples) occurred simultaneously with the post-application exposure activities rather than before them.

- According to the guidelines, inhalation exposure studies must be carried out concurrently with dermal exposure and transferable residue studies. Transferable residue studies were not performed concurrently with this study and only applicator hand exposure was monitored.

- Indoor sampling devices for air monitoring were set at 5 feet above the floor to simulate an adult's breathing zone. There were no samplers set lower to the floor to represent exposure to children.

- The results for the method validation were presented in the study report without addressing what matrix was used. The limit of detection (LOD) for this method was 5.0 picograms (5.0E-06 µg). The limit of quantitation (LOQ) for this method was not provided.

- There was no recovery data provided in this study to determine if correction of the raw data was required.

B. CONCLUSIONS:

The purpose of the study was to determine the level of exposure to naphthalene when used as an insecticide under conditions representing typical use situations. Concentration of volatile naphthalene was determined by collection of air samples at regular intervals after treatment and for specific durations of time. Dermal exposure to the applicator was determined by analysis of gloves worn when weighing out and applying the test product. The overall average naphthalene applicator hand exposure was either 9.91E-05 or 1.30E-04 mg/cm^2, depending on whether or not an unidentified sample provided in the report can be clarified. Applicator inhalation exposure data were not provided even though the Study Report mentions collection of this data. Post-application inhalation exposure and air concentrations were monitored on Days 4, 5 and 6 after the application. The overall average post-application inhalation exposures for Days 4, 5 and 6 were 773 µg $/m^3$ (123 µg/day), 867 µg $/m^3$ (217 µg/day) and 900 µg $/m^3$ (225 µg/day), respectively. Air monitoring took place within the treated zones (dresser drawer and closed closet). However, the Study Author only provided naphthalene air concentrations for Hour 0, Hours 4-8, and Hour 12. These concentrations ranged for all three trials from 2.37 to 10.3 µg/L in the dresser drawer and from 1.49 to 12.29 µg/L in the closet for all three days. The air sampling devices monitoring the areas outside the treated zone were placed just outside the closet, on top of the dresser and adjacent to the head of the bed.

The average 24-hour naphthalene air concentration on top of the dresser at all three test sites on Days 4, 5 and 6 ranged from 0.39 to 0.89 µg/L. The average 24-hour naphthalene air concentration adjacent to the closet at all three test sites on Days 4, 5 and 6 ranged from 0.43 to 0.81 µg/L. The average 24-hour naphthalene air concentration at the head of the bed at all three test sites on Days 4, 5 and 6 ranged from 0.39 to 0.86 µg/L.

Table 2. Applicator Hand Exposure (mg/cm^2) Based on Cotton Glove Dosimeters.

Trial	Naphthalene Residue - Both Hands (mg)	Contact Surface Area of Both Gloves (cm^2)	Naphthalene Hand Exposure (mg/cm^2)
92-298-01-21H-02	0.00807	407	1.98E-05
92-298-01-21H-03	0.104	407	2.56E-04
92-298-01-21H-04	0.0465	407	1.14E-04
Unknown	0.00279	407	6.85E-06
Mean (w/ unknown) Mean (w/o unknown)	0.040 0.053	407	9.91E-05 1.30E-04

Note: Even though the entire glove was extracted and analyzed, dermal exposure was calculated assuming that all of the naphthalene residue found on the gloves corresponded to the area of palm and fingers (contact side).

Table 3. Post-Application Inhalation Exposure (µg/day)										
Site #	Average Day 4 Naphthalene Air Concentration (µg/L)	Average Day 5 Naphthalene Air Concentration (µg/L)	Average Day 6 Naphthalene Air Concentration (µg/L)	Breathing Rate L/min	Day 4 Concentration (µg/m3)	Day 5 Concentration (µg/m3)	Day 6 Concentration (µg/m3)	Day 4 Exposure (µg/day)	Day 5 Exposure (µg/day)	Day 6 Exposure (µg/day)
92-298-01-21H-02	0.490	0.480	0.630	16.7	490.0	480.0	630.0	123	120	158
92-298-01-21H-03	0.850	1.12	1.33	16.7	850.0	1120.0	1330.0	213	281	333
92-298-01-21H-04	0.980	1.00	0.740	16.7	980.0	1000.0	740.0	245	251	185
Overall Average					773	867	900	194	217	225
Std Dev.					254	340	376	64	85	94

Notes:
1. Concentration ($\mu g/m^{33}$) = Residue (µg/L sample) x 1,000 (L/m^3)
2. Exposure (µg/day) = Concentration (µg/L) x Breathing Rate (L/min) x 15 min/day

Table 4. Concentration of Naphthalene in Dresser Drawer and Closet (µg/L)						
Hours	Day 4		Day 5		Day 6	
	Drawer	Closet	Drawer	Closet	Drawer	Closet
92-298-01-21H-02						
0	9.80	1.94	6.99	1.17	5.29	1.94
4 to 8	9.41	3.22	7.95	2.42	10.3	3.01
12	5.41	1.49	6.04	1.78	10.2	2.20
92-298-01-21H-03						
0	3.66	9.10	5.20	12.29	5.61	8.13
4 to 8	4.54	10.7	4.77	10.18	4.79	9.23
12	4.32	10.02	4.26	8.84	4.5	9.51
92-298-01-21H-04						
0	3.06	5.99	3.35	4.57	2.50	4.39
4 to 8	2.83	3.78	3.84	5.12	9.45	4.06
12	2.37	5.08	8.6	4.23	5.9	3.71

Note: Sampling devices were placed inside the open dresser drawer and on the wall inside the treated closet approximately 5 ft. from above the floor.

Table 5. Air Concentration of Naphthalene in Room (µg/L)									
Hours	Average Day 4 Naphthalene Air Concentration Adjacent to Dresser Drawer (µg/L)	Average Day 5 Naphthalene Air Concentration Adjacent to Dresser Drawer (µg/L)	Average Day 6 Naphthalene Air Concentration Adjacent to Dresser Drawer (µg/L)	Average Day 4 Naphthalene Air Concentration Adjacent to Closet (µg/L)	Average Day 5 Naphthalene Air Concentration Adjacent to Closet (µg/L)	Average Day 6 Naphthalene Air Concentration Adjacent to Closet (µg/L)	Average Day 4 Naphthalene Air Concentration Adjacent to Bed (µg/L)	Average Day 5 Naphthalene Air Concentration Adjacent to Bed (µg/L)	Average Day 6 Naphthalene Air Concentration Adjacent to Bed (µg/L)
92-298-01-21H-02									
0 – 8	0.48	0.41	0.36	0.50	0.44	0.64	0.52	0.37	0.64
8 – 16	0.45	0.50	0.69	0.53	0.53	0.72	0.39	0.46	0.66
16 - 24	0.24	0.52	0.92	0.27	0.61	0.81	0.25	0.58	0.83
Avg.	0.39	0.48	0.66	0.43	0.53	0.72	0.39	0.47	0.71
92-298-01-21H-03									
0 – 8	0.76	0.93	1.10	0.73	0.86	0.98	0.68	0.87	1.03
8 – 16	0.94	1.05	1.02	0.95	0.95	0.91	0.99	1.05	0.98
16 - 24	0.73	0.66	0.55	0.71	0.60	0.54	0.58	0.66	0.57
Avg.	0.81	0.88	0.89	0.80	0.80	0.81	0.75	0.86	0.86
92-298-01-21H-04									
0 – 8	0.65	0.64	0.57	0.73	0.91	0.63	0.65	0.60	0.56
8 – 16	0.71	0.63	0.47	0.92	0.69	0.56	0.72	0.54	0.43
16 - 24	0.55	0.49	0.50	0.77	0.67	0.62	0.52	0.47	0.41
Avg.	0.64	0.59	0.51	0.81	0.76	0.60	0.63	0.54	0.47

Notes:

1. Sampling devices were placed on top of the dresser, adjacent to the closet door approximately 5 ft above the floor and adjacent to the bed approximately 5 ft above the floor

The following is a checklist for OPPTS Series 875, Occupational and Residential Exposure Test Guidelines, Group A, Guideline 875.1200 (DERMAL EXPOSURE- INDOOR).

- *Investigators should submit protocols for review purposes prior to the inception of the study.* It is not certain if this criterion was met. A study protocol was not provided in this study.

- *Expected deviations from GLPs should be presented concurrently with any protocol deviations and their potential study impacts.* This criterion was met.

- *The test substance should be a typical end use product of the active ingredient.* This criterion was met.

- *The application rate used in the study should be provided and should be the maximum rate specified on the label. However, monitoring following application at a typical application rate may be more appropriate in certain cases.* It is uncertain if this criterion was met. The label provided by EPA did not specify an application rate.

- *Selected sites and indoor conditions of monitoring should be appropriate to the activity.* This criterion was met.

- *A sufficient number of replicates should be generated to address the exposure issues associated with the population of interest. For indoor exposure monitoring, each study should include a minimum of 15 individuals (replicates) per activity.* This criterion was not met. Only three applicators were monitored in this study.

- *The quantity of active ingredient handled and the duration of the monitoring period should be reported for each replicate.* These criteria were partially met. The quantity of active ingredient handled was provided. The duration of each application at each residence was not reported.

- *Test subjects should be regular workers, volunteers trained in the work activities required, or typical homeowners.* It is not certain if this criterion was met. Information about the workers in this study was not provided in the Study Report.

- *Any protective clothing worn by the test subjects should be identified and should be consistent with the product label.* It is not certain if this criterion was met. The protective clothing worn by the applicators was not identified and the label provided by EPA did not list protective equipment to be worn when handling the formulated product, only the technical form.

- *The monitored activity should be representative of a typical working day for the specific task in order to capture all related exposure activities.* This criterion was partially met. Although application to one bedroom may be typical, it is possible that a resident could apply to more than one bedroom in a single day.

- *Dermal exposure pads used for estimating dermal exposure to sprays should be constructed from paper-making pulp or similar material (i.e., alpha-cellulose), approximately 1 mm thick, that will absorb a considerable amount of spray without disintegrating. The alpha-cellulose material should not typically require pre-extraction to remove substances that interfere with residue analysis. This should be determined prior to using the pads in exposure tests.* This criterion does not apply to this study.

- *Dermal exposure pads used for estimating dermal exposure to dust formulations, dried residues, and to dust from granular formulation should be constructed from layers of surgical gauze. The pad should be bound so that an area of gauze at least 2.5 inch square is left exposed. The gauze must be checked for material that would interfere with analysis and be pre-extracted if necessary.* This criterion does not apply to this study.

- *A complete set of pads for each exposure period should consist of 10 to 12 pads. If the determination of actual penetration of work clothing is desired in the field study, additional pads can be attached under the worker's outer garments. Pads should be attached under both upper and lower outer garments, particularly in regions expected to receive maximum exposure. Pads under clothing should be near, but not covered by, pads on the outside of the clothing.* This criterion does not apply to this study.
- *If exposed pads are to be stored prior to extraction, storage envelopes made from heavy filter paper may be used. The envelope must be checked for material that will interfere with analysis. Unwaxed sandwich bags should be used to contain the filter paper envelopes to help protect against contamination.* This criterion does not apply to this study.

- *Hand rinses should be performed during preliminary studies to ensure that interferences are not present. Plastic bags designed to contain 0.5 gal and strong enough to withstand vigorous shaking (i.e., at least 1 mil inch thickness) should be used. During preliminary studies, plastic bags must be shaken with the solvent to be used in the study to ensure that material which may interfere with analysis is not present.* This criterion does not apply to this study.

- *The analytical procedure must be capable of quantitative detection of residues on exposure pads at a level of 1 ug/cm^2 (or less, if the dermal toxicity of the material under study warrants greater sensitivity).* This criterion does not apply to this study.

- *The extraction efficiency of laboratory fortified controls is considered acceptable if the lower limit of the 95% confidence interval is greater than 75%, unless otherwise specified by the Agency. At a minimum, seven determinations should be made at each fortification level to calculate the mean and standard deviation for recovery. Total recovery from field-fortified samples must be greater than 50% for the study.* These criteria were not met. Laboratory fortification recoveries were not discussed in this study. Field fortification samples were prepared but the results were not discussed in this study.

- *If the stability of the material of interest is unknown, or if the material is subject to degradation, the investigator must undertake and document a study to ascertain loss of residues while the pads are worn. It is recommended that collection devices be fortified with the same levels expected to occur during the field studies. The dosimeters should be exposed to similar indoor conditions and for the same time period as those expected during field studies.* This criterion was not met. Field fortification samples, which may or may not have been subjected to the same conditions as the field samples were not reported.

- *Data should be corrected if any appropriate field fortified, laboratory fortified or storage stability recovery is less than 90 percent.* This criterion was not met. The study did not provide data for field or laboratory fortification results.

- *Field data should be documented, including chemical information, area description, environmental conditions, application data, equipment information, information on work activity monitored, sample numbers, exposure time, and any other observations.* These criteria were partially met. Thoroughly documented field data were not provided with the study. Equipment calibration information, monitoring durations, and worker details were not provided in the study.

- *A sample history sheet must be prepared by the laboratory upon receipt of samples.* It is not certain if this criterion was met.

The following is a checklist for OPPTS Series 875, Occupational and Residential Exposure Test Guidelines, Group A, Guideline 875.1400
INHALATION EXPOSURE- INDOOR

NOTE: Indoor inhalation applicator levels were not reported. The Study Report does mention that the samples were collected however.

- *Investigators should submit protocols for review purposes prior to the inception of the study.* It is not certain if this criterion was met. A study protocol was not provided in this study.
- *Expected deviations from GLPs should be presented concurrently with any protocol deviations and their potential study impacts.* This criterion was met.
- *The test substance should be a typical end use product of the active ingredient.* This criterion was met.
- *The application rate used in the study should be provided and should be the maximum rate specified on the label. However, monitoring following application at a typical application rate may be more appropriate in certain cases.* It is uncertain if this criterion was met. The label provided by EPA did not specify an application rate.
- *Selected sites and indoor conditions of monitoring should be appropriate to the activity.* This criterion was met.
- *A sufficient number of replicates should be generated to address the exposure issues associated with the population of interest. For outdoor exposure monitoring, each study should include a minimum of 15 individuals (replicates) per activity.* This criterion was not met. There were 3 indoor applicator replicates for this study.
- *The quantity of active ingredient handled and the duration of the monitoring period should be reported for each replicate.* These criteria were partially met. The quantity of active ingredient handled was provided. The duration of each application at each residence was not reported.
- *Test subjects should be regular workers, volunteers trained in the work activities required, or typical homeowners.* It is not certain if this criterion was met. Information about the workers in this study was not provided in the Study Report.
- *The monitored activity should be representative of a typical working day for the specific task in order to capture all related exposure activities.* This criterion was partially met. Although application to one bedroom may be typical, it is possible that a resident could apply to more than one bedroom in a single day.
- *When both dermal and inhalation monitoring are required, field studies designed to measure exposure by both routes on the same subjects may be used.* This criterion was met.
- *The analytical procedure must be capable of measuring exposure to 1 ug/hr (or less, if the toxicity of the material under study warrants greater sensitivity).* This criterion was met.
- A *trapping efficiency test for the monitoring media chosen must be documented.* This criterion was not met. Results for a trapping efficiency study were not provided in the study.
- *Air samples should also be tested for breakthrough to ensure that collected material is not lost from the medium during sampling. It is recommended that at least one test be carried out where the initial trap contains 10X the highest amount of residue expected in the field.* It is not certain if this criterion was met.

- *The extraction efficiency of laboratory fortified controls is considered acceptable if the lower limit of the 95% confidence interval is greater than 75%, unless otherwise specified by the Agency. At a minimum, seven determinations should be made at each fortification level to calculate the mean and standard deviation for recovery. Total recovery from field-fortified samples must be greater than 50% for the study.* These criteria were not met. Laboratory fortification recoveries were not discussed in this study. Field fortification samples were prepared but the results were not discussed in this study.

- *If trapping media or extracts from field samples are to be stored after exposure, a stability test of the compound of interest must be documented. Media must be stored under the same conditions as field samples. Storage stability samples should be extracted and analyzed immediately before and at appropriate periods during storage. The time periods for storage should be chosen so that the longest corresponds to the longest projected storage period for field samples.* These criteria were not met. Storage stability was not discussed in this study.

- *A personal monitoring pump capable of producing an airflow of at least 2 L/min. should be used and its batteries should be capable of sustaining maximum airflow for at least 4 hours without recharging. Airflow should be measured at the beginning and end of the exposure period.* These criteria were partially. The personal monitoring pump operated in this study was operated at an airflow of 0.5 L/min. It is not known if the pump was capable of operating at 2 L/min. The study stated that the airflow was measured before and after each exposure period but the measurements were not provided in the study.

- *Appropriate air sampling media should be selected. The medium should entrap a high percentage of the chemical passing through it, and it should allow the elution of a high percentage of the entrapped chemical for analysis.* It is not certain if this criterion was met or not. No field fortification results are reported.

- *If exposed media are to be stored prior to extraction, storage envelopes made from heavy filter paper may be used. The envelope must be checked for material that will interfere with analysis. Unwaxed sandwich bags should be used to contain the filter paper envelopes to help protect against contamination.* This criterion was met.

- *Personal monitors should be arranged with the intake tube positioned downward, as near as possible to the nose level of the subject. The height of the intake tube is especially important when taking samples indoors where walls or ceilings are being sprayed.* This criterion was met.

- *Field calibration of personal monitors should be performed at the beginning and end of the exposure period.* It is not certain if this criterion was fully met. The study stated that the monitors were calibrated before the exposure period but did not mention calibration at the end of the exposure period.

- *Field fortification samples and blanks should be analyzed for correction of residue losses occurring during the exposure period. Fortified samples and blanks should be fortified at the expected residue level of the actual field samples. Fortified blanks should be exposed to the same indoor conditions.* These criteria were partially met. Field fortification samples were prepared but the results were not provided in the study.

- *Respirator pads should be removed using clean tweezers and placed in protective white crepe filter paper envelopes inside sandwich bags. The pads should be stored in a chest containing ice until they are returned to the laboratory, where they should be stored in a freezer prior to extraction.* This criterion does not apply to this study.

- *Field data should be documented, including chemical information, area description, environmental conditions, application data, equipment information, information on work activity monitored, sample numbers, exposure time, and any other observations.* These criteria were not

met. Thoroughly documented field data were not provided with the study. Equipment calibration information, monitoring durations, and worker details were not provided in the study. Results are not provided.

- *Analysis methods should be documented and appropriate.* This criterion was met.
- *A sample history sheet must be prepared by the laboratory upon receipt of samples.* This criterion was not met.

The following is a checklist for OPPTS Series 875, Occupational and Residential Exposure Test Guidelines, Group B, Guideline 875.2500
INHALATION EXPOSURE MONITORING
POSTAPPLICATION

- *The production of metabolites, breakdown products, or the presence of contaminants of potential toxicologic concern, should be considered on a case-by-case basis.* It is not certain if this criterion was met. The study did not mention metabolites or breakdown products.

- *Applications should occur at the time of season that the end-use product is normally applied to achieve intended pest control.* This criterion is not applicable for indoor applications.

- *Initiating testing immediately before a precipitation event should be avoided.* This criterion is not applicable.

- *The end use product should be applied by the application method recommended for the crop. Information that verifies that the application equipment (e.g., sprayer) was properly calibrated should be included.* It is uncertain if the criteria which apply to this study were met. The product was applied by hand but a label describing the method of application was not available. The calibration of application equipment does not apply to this study.

- *If multiple applications are made, the minimum allowable interval between applications should be used.* This criterion was not applicable for this type of study. Only one application was made.

- *The monitoring period should be of sufficient duration to result in reasonable detectability on dosimeters. Monitoring should be conducted before residues have dissipated beyond the limit of quantification. Baseline samples should be collected before the exposure activity commences.* These criteria were met. Background levels of naphthalene were determined by collecting air in an untreated room located away from the treated room at each location. The sampling method and duration was the same as that used for collection of the stationary air monitoring samples from the treated room (outside the treated zones). Samples of air were collected in 8-hour increments on days 4, 5 and 6. Therefore, background sampling occurred simultaneously with the post-application exposure activities rather than before them.

- *Activities monitored must be clearly defined and representative of typical practice.* This criterion was met.

- *Inhalation exposure studies must be carried out concurrently with dermal exposure and transferable residue studies.* This criterion was partially met. Transferable residue studies were not performed concurrently with this study. Only applicator hand exposure was studied. There were no post-application dermal exposure studies performed concurrently.

- *The selected sites and seasonal timing of monitoring must be appropriate to the activity.* This criterion is not applicable for this type of indoor study.

- *Studies should be conducted under different geographic/climatologic sites.* This criterion was not met; however, this study was conducted in indoor climate controlled rooms. The study was performed at three indoor locations within the Valdosta, Georgia area.

- *Inhalation monitoring techniques area (i.e., stationary) and/or personal monitoring) should contain sufficient samples to characterize the likely range of possible exposure concentrations, and to ensure that the reentry scenario can be adequately addressed.* This criterion was probably met.

- *Particulate levels should be monitored along with vapor phase concentrations unless adequate justification for not doing so is provided.* In this study only volatilized naphthalene was collected

by adsorption on charcoal.

- *The sampling technique used should be appropriate, given the expected exposure scenario (e.g., the use of personal sampling pumps and sampling times consisting of filter cassettes and resin tubes or polyurethane foam filters is preferred; where personal sampling is not appropriate, stationary monitoring may be conducted.)* This criterion was met.

- *Personal sampling pumps should be clipped to the collar in the breathing zone of the test subject.* This criterion was met.

- *Stationary samples should be collected from the center of treated fields and from at least 4 other locations, preferably at the cardinal compost points from the center location.* This criterion was met. Stationary samples were collected from within the treated zones (closed closet and closed dresser drawer) as well as three additional adjacent areas within the same room (outside and adjacent to treated closet, on top of treated dresser and adjacent to head of bed).

- *Indoor sampling strategies should be designed based on the nature of the exposure scenario and building type. Samples should be collected at heights representing the breathing zones of the exposed populations (e.g., 18 inches for children; 48 inches for adults).* This criterion was partially met. An air sampler was placed at 5 feet above the floor in the treated closet, just outside the closet and above the head of the bed. There were no samplers set lower to the floor to represent exposure to children.

- *The duration of the sampling interval and air flow rates should be maximized within the appropriate flow rate range to increase the potential for capturing enough residue to be quantifiable.* This criterion was not met. The flow rate used was not maximized and was set at 0.5 L/min.

- *Air flow rates should be recorded at the initiation and termination of the monitoring period, with the average being used in all calculations.* It is not certain if this criterion was met. The study did not specify whether flow rates were recorded at the initiation and termination of the monitoring period.

- *Validated analytical methods of sufficient sensitivity are needed. Information on method efficiency (residue recovery) and limit of quantification (LOQ) should be provided.* These criteria were partially met. Field fortification and laboratory fortification recovery results were not provided. The limit of detection (LOD) for this method was 5.0 picograms (5.0E-06 µg). The limit of quantitation (LOQ) for this method was not provided in the Study Report. Method validation results were given but the matrix used in the validation was not stated.

- *Raw residue data must be corrected if appropriate recovery values are less than 90 percent.* This criterion was not met. There was no recovery data provided in this study.

- *Residues should be reported as µg pesticide active ingredient per sample and as an airborne concentration ($\mu g/m^3$).* Distributional data should be reported, to the extent possible. These criteria were partially met. The study reported residues as µg/L, µg/hr and, µg/kg.

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R158146

Chemical: Naphthalene

PC Code:
055801

HED File Code: 12000 Exposure Reviews
Memo Date: 2/17/2008
File ID: DPD340008
Accession #: 000-00-0124

HED Records Reference Center
3/31/2008